REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

The Office Action:

a) objected to claims 9 and 16 for allegedly utilizing improper Markush language;

b) rejected claims 14 - 17 under 35 USC §112, second paragraph, as allegedly being indefinite;

c) rejected claims 1 – 5 and 7 - 17 under 35 USC §112, second paragraph, as allegedly being indefinite; and

d) rejected claims 1 – 5 and 7 - 17 under 35 USC §103(a) as allegedly being unpatentable over United States Patent No. 4,835,187 to Reuter ("Reuter") in view of Lachman, et al., The Theory and Practice of Industrial Pharmacy ("Lachman").

Claims 9 and 16 were amended to overcome the informalities objection. Applicants respectfully submit that this amendment does not narrow the scope of the claims for reasons related to patentability, and that the objection to claims 9 and 16 for allegedly utilizing improper Markush language has been overcome and should be withdrawn.

Claim 6 was withdrawn as being directed to a non-elected invention, and Claims 1 – 5 and 7 – 17 remain pending in this application after entry of this response.

I. The rejection of claims 14 - 17 under 35 USC §112, second paragraph, as being indefinite should be withdrawn.

Claims 14 – 17 stand rejected under 35 USC §112, second paragraph, as being allegedly indefinite. Applicants respectfully disagree for the reasons that follow.

According to the Office Action, "the phrase 'substantially free' is not defined within said claim, the instant specification does not appear to provide a standard for ascertaining the requisite degree of what constitutes 'substantially free' of hydroxyl propylmethylcellulose, and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention." Applicants respectfully disagree.

The Specification as originally filed on page 3, lines 26 – 30 clearly sets forth that

> [i]n one embodiment, the granulated active ingredient particles are substantially free of high weight average molecular weight hydroxylalkylcellulose. As used herein, "**substantially free of high weight average molecular weight hydroxyalkylcellulose**" shall mean that the granulated particles contain, based upon the total weight of the particles, less than about 1%, e.g., less than about 0.1% or less than about 0.01% of high weight average molecular weight hydroxyalkylcellulose .

(emphasis added).

The Specification as originally filed on page 3, lines 14 – 16 also clearly set forth the meaning of "high weight average molecular weight hydroxyalkylcellulose:"

> a hydroxyalkylcellulose having a) weight average molecular weight between about 60,000 to about 5,000,000m and/or b) a viscosity between about 3000 mPa.s to about 150,000 mPa.s in a 2% aqueous solution....

Therefore, in view of the disclosure expressly set forth in the Specification as originally filed, Applicants respectfully submit that one skilled in the art would readily understand the meaning of "substantially free of hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 and/ or a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution" as used in claim 14.

Applicants also wish to point out that although the "particles comprised of a pharmaceutically active ingredient are substantially free of hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000...," the claimed dosage form of claim 14 still contains "a matrix comprising, based upon the total weight of the dosage form, from about 0.1 percent to about 25 percent of hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000...." (emphasis added).

In view of the above, Applicants respectfully submit that, the rejection of claims 14 – 17 under 35 USC §112, second paragraph, has been overcome and should be withdrawn.

II. The rejection of claims 1 – 5 and 7 - 17 under 35 USC §112, second paragraph, as <u>being indefinite should be withdrawn.</u>

Claims 1 – 5 and 7 - 17 stand rejected under 35 USC §112, second paragraph, as being allegedly indefinite. Applicants respectfully disagree for the reasons that follow.

According to the Office Action, "the phrase 'and/or' renders [claims 1 and 14] indefinite because the meets and bounds of said claims is [allegedly] unclear," citing MPEP § 2173.05(d).

Applicants wish to point out that the MPEP §2173.02 expressly provides that:

> [o]ffice policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP §2173.05(d) are fact specific and should <u>not</u> be applied as *per se* rules. The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.' <u>Orthokinetics, Inc. v. Safety Travel Chairs, Inc</u>. 806 F.2d 1565, 1576, 1 USPQ.2d 1081, 1088 (Fed. Cir. 1986).

Applicants respectfully submit that one skilled in the art, who has read the claim in light of the specification, would readily understand that the hydroxyalkylcellulose in the matrix may possess:

(1) "a weight average molecular weight of from about 60,000 to about 5,000,000 [AND] a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution;" or

(2) "a weight average molecular weight of from about 60,000 to about 5,000,000 [BUT NOT] a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution;" or

(3) "a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution" BUT NOT "a weight average molecular weight of from about 60,000 to about 5,000,000."

Further, Applicants question the Office Action's comment that "confusion exists with respect to the intended scope of said claims" when in fact the above interpretation is similar to that described by the Examiner in the Office Action.

Thus, in view of the above, Applicants respectfully submit that, the rejection of claims 1 – 5 and 7 - 17 under 35 USC §112, second paragraph, has been overcome and should be withdrawn.

III. The rejection of claims 1 – 5 and 7 - 17 under 35 USC §103(a), as being unpatentable over Reuter in view of Lachman should be withdrawn.

Claims 1 – 5 and 7 - 17 stand rejected under 35 USC §103(a), second paragraph, as being allegedly unpatentable over Reuter in view of Lachman. Applicants respectfully disagree for the reasons that follow.

According to the Office Action, Reuter "teaches an immediate release composition in chewable solid dosage form comprising: a plurality of inert silica particles... comprising ibuprofen, [and] USP hydroxypropylmethylcellulose grades E, F, and K ..." (emphasis added). However, the Office Action has failed to point out where Reuter discloses or suggests the use of "hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 and/ or a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution" in a matrix.

By contrast, the dosage form claimed in claim 1 is comprised of (a) "a plurality of particles comprising a pharmaceutically active ingredient...;" and (b) "a matrix comprising, based upon the total weight of the dosage form, from about 0.1 percent to about 25 percent of hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 and/ or a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution." (emphasis added).

In sum, the Office Action has failed to point out where Reuter or Lachman discloses or suggests the use of the claimed hydroxyalkylcellulose in the matrix as claimed, let alone the use of "from about 0.1 percent to about 25 percent" of such hydroxyalkylcellulose in the matrix as claimed. Rather, the disclosure of Reuter is limited to the use of a "USP hydroxypropylmethylcellulose grades E, F, and K" in its particles, which in fact is also contrary to the embodiment claimed in claim 14 that particularly provides:

> the plurality of particles comprised of a pharmaceutically active ingredient are substantially free of hydroxyalkylcellulose...

(emphasis added).

Therefore, in view of the above, Applicants respectfully submit that the rejection of claims 1 – 5 and claims 7 – 17 under 35 USC §103(a) has been overcome and should be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,

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